## **REMARKS**

This amendment is responsive to the Non-Final Office Action of November 13, 2007. Reconsideration and allowance of claims 1-18, 31-32 and 34-39 are requested.

Claim 31 has been amended.

Claim 33 has been cancelled, without prejudice.

Claims 19-30 were previously cancelled.

## **The Office Action**

Claims 1-2, 6-7, 10-13, 15, and 37-39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,071,437 to Ryan, Jr., et al., in view of U.S. Patent No. 7,067,089 to Wen and U.S. Pub. No. 2003/0085147 to Gabriele.

Claim 3 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan, Jr., et al., in view of Wen and Gabriele, and further in view of U.S. Patent No. 4,241,010 to Baran.

Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan, Jr., et al., in view of Wen and Gabriele, and further in view of DE Publication No. 19537630 A1 to Adamski (Automated translation).

Claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan, Jr., et al., in view of Wen and Gabriele, and further in view of U.S. Patent No. 4,111,753 to Folsom, et al.

Claims 14 and 16-18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan, Jr., et al., in view of Wen and Gabriele, and further in view of U.S. Patent No. 4,317,521 to Clark.

Claims 31 and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan, Jr., et al., in view of U.S. Patent No. 5,792,435 to Mueller, et al., and further in view of Folsom, et al.

Claims 33 and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan, Jr., et al., in view of Mueller, et al., and Folsom, et al., and further in view of Gabriele.

Claim 35 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan, Jr., et al., in view of Mueller, et al., Folsom, et al., and Gabriele, and further in view of Baran.

Claim 36 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan, Jr., et al., in view of Mueller, et al., Folsom, et al., Gabriele, and Baran, and further in view of Adamski.

## The Claims Distinguish Patentably Over The References of Record

Claim 1 calls for a method for handling items that includes three steps:

- 1. Sorting potentially contaminated items in an enclosure to separate items which are unsuited to treatment with a first decontaminant from remaining items,
- 2. Treating at least a portion of the sorted items with a first decontaminant capable of destroying the pathogenic agent, and
  - 3. Treating the enclosure with a second decontaminant.

The references of record do not disclose or suggest a method as claimed. Ryan, Jr., et al. discloses a system for detecting harmful materials in a mail stream. A sorting apparatus 8 includes a feeder 10, a singulator 12, an OCR scanner 14, a transporter 16, and a bin module 20. The singulator separates all the mail so that each item can be processed singly in a sanitization area 44 (FIG. 5c) in sanitizer 13. The singulator of Ryan thus does not perform a sorting function as presently claimed. As shown in FIGURE 5a, the mail is not sorted until after it has passed through the sanitizer. Thus, all mail (unsorted mail) is treated by the sanitizer, whether or not it contains harmful materials or is amenable to processing. Thus, Ryan does not disclose treating sorted items with a first decontaminant and treating an enclosure where the mail is sorted with a second decontaminant.

Wen discloses a sanitizing device which includes a conveyor belt 12 for carrying envelopes, packages, and the like. A uv/microwave source 24 is provided for irradiating a sanitizing zone 19. Upstream of the zone 19, a sensing device 17 recognizes magnetic packages and shunts them aside to avoid exposure to the microwave radiation. There is no suggestion in Wen that the package removal step be performed in an enclosure or that a second decontaminant be used to treat such an enclosure.

Gabriele discloses an aseptic enclosure 30 formed of a thin film material. The enclosure is designed to be placed over medical equipment and is held in place with an elastic band. The thin film is made from a flexible polymer and, after thermoforming into the shape of the enclosure, is only 2-3 mils in thickness. After use, the enclosure can be removed from the medical device and washed in an antiseptic solution.

The Examiner argues that Gabriele discloses "a method of decontaminating an enclosure with potentially contaminated items in the enclosure (paragraphs 2-4)." Applicants submit that this is not the case. The medical equipment covered by Gabriele's enclosure is equipment which is <u>subject</u> to contamination. The purpose of the enclosure is clearly to prevent the medical equipment from becoming contaminated, i.e., to maintain its sterility prior to surgery, not to enclose potentially contaminated items. The contamination of the enclosure 30, if any, is exterior to the enclosure, as suggested by the last sentence of paragraph [0002].

The Examiner argues that it would have been obvious "to modify the method of Ryan in view of Wen to decontaminate the enclosure in order to provide a sterile enclosure for items that may be placed in the enclosure in the future, as exemplified by Gabriele." Applicants respectfully traverse.

First, Gabriele washes the enclosure in antiseptic so that is aseptic in order to cover <u>clean</u> medical equipment, not to receive contaminated or potentially contaminated equipment. Gabriele provides no motivation for cleaning an enclosure which is to receive or which has received potentially contaminated items to be sorted.

Second, the Examiner has not identified in Ryan or Wen any enclosure where sorting takes place prior to decontamination which could be cleaned by Gabriele's washing process. Wen's sorting does not take place in an enclosure. Ryan's sorting takes place after decontamination. Thus, there is no enclosure, as claimed, which could benefit from Gabriele's cleaning.

Third, it would not be obvious to use a thin flexible film, as taught by Gabriele, which is presumably not self supporting, to enclose Wen's likely sizeable region where items are examined with an X-ray machine.

The secondary references cited against the dependent claims do not supply the deficiencies of Ryan, Wen, and Gabriele. In particular, Baran cited against claim 3, Adamski, cited against claims 4 and 5, Clark cited against claims 14 and 16-18, and Folsom cited against clams 8 and 9, disclose no pre-sorting step nor treatment of an enclosure in which sorting of potentially contaminated items takes place, as presently claimed. Further, the references do not suggest treating with one decontaminant in an enclosure and treating with a second decontaminant in a chamber.

Accordingly, it is submitted that claim 1, and claims 2-5, 8-18, and 37-38 dependent therefrom, distinguish patentably and unobviously over the references of record.

Claim 6 recites a method for handling items potentially contaminated with a pathogenic agent which includes sorting the potentially contaminated items in an enclosure, and thereafter treating at least a portion of the sorted items with a first decontaminant capable of destroying the pathogenic agent in a chamber which is selectively connected with the enclosure and is isolatable from the enclosure and treating the enclosure in which the items are sorted with a second decontaminant.

The combination of Ryan with Wen and Gabriele does not disclose a method in which potentially contaminated items are first sorted in an enclosure and then a portion of these items treated in an isolatable chamber. Ryan teaches sanitizing all items prior to sorting. Wen does some sorting of items, but not in an enclosure. Gabriele neither sorts items in an enclosure nor places potentially contaminated items in an enclosure. There is no suggestion in the cited references, taken singly or in combination, of sorting potentially contaminated items in an enclosure or of a chamber which is isolatable from such an enclosure.

Accordingly, it is submitted that claims 6, 7, and 39 distinguish over the references of record.

Claim 31 recites a method for handling items potentially contaminated with a pathogenic agent. Items are transported in a sealed container which is connected to an isolated enclosure in an airtight manner. The items are sorted within the isolated enclosure. A portion of the sorted items is moved into a sealable decontamination chamber where the items are treated with a first decontaminant. While this takes place, additional items are received and sorted in the isolated enclosure.

Claim 31 has been amended to incorporate the subject matter of claim 33. Claim 33 was rejected over Ryan, Mueller, Folsom, and Gabriele. Ryan does not suggest moving sorted items into a sealable decontamination chamber for treatment. Rather, items are treated in a conveyor system prior to sorting. Mueller discloses a flow through vapor phase decontamination apparatus which receives a load of medical instruments, containers or the like. There is no sorting of these items not any motivation suggested for doing so. Folsom discloses a controlled atmosphere apparatus in which anaerobes can be grown and manipulated. There is no suggestion of using the system for sorting items nor any suggestion for doing so.

The Examiner argues that it would have been obvious to modify the method of Ryan, Mueller and Folsom in view of Gabriele to decontaminate the enclosure to provide a sterile environment for items that may be placed in the enclosure in the future.

Applicants respectfully traverse. Gabriel teaches washing a flexible enclosure which is to be used to cover medical equipment. There is no suggestion that such a washing method could be used to render an enclosure for Ryan's singulator antiseptic nor any motivation for doing so.

Accordingly, it is submitted that claims 31-32 and 34-36 distinguish over the references of record.

## **CONCLUSION**

For the reasons set forth above, it is submitted that claims 1-18, 31-32 and 34-39 distinguish patentably and unobviously over the references of record and are now in condition for allowance. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is requested to telephone Thomas Kocovsky at (216) 861-5582.

Respectfully submitted,

FAY SHARPE LLP

Thomas E. Kocovsky, Jr., Reg. No. 28,383

Ann M. Skerry, Reg. No. 45,65

1100 Superior Avenue, 7th Floor

Cleveland, OH 44114-2579

(216) 861-5582

N:\MEDZ\201312\US\TLL0002151V001.DOC